VERMONT

Vermont Health Access
Pharmacy Benefit Management Program
DUR Board Meeting Minutes: 04/03/07

Board Members:

Michael Scovner, M.D., Chair
Andrew Miller, R. Ph.
Cheryl Gibson, M.D.
Norman Ward, M.D.
Frank Landry, M.D.
Stuart Graves, M.D.
Virginia Hood, M.D.

Staff:

Ann Rugg, OVHA
Diane Neal, R.Ph., (MHP)
Jennifer Mullikin, OVHA
Scott Strenio, M.D., OVHA
Nancy Miner, (MHP)
Sandi Drury, (MHP)
Christopher Ciano, R.Ph., (MHP)
Robin Farnsworth, OVHA
Stacey Baker, OVHA

Guests:

Carl Marchand, AstraZeneca
Carl Pepe, GSK
Dan Doucette, Purdue
Glenn E. Dooley, Sr, Sanofi-Aventis
Jenifer Buttle, Merck
Keith White, Genentech
Kevin Boehmcke, Abbott
Kevin Danielson, Pfizer
Kirt Hyles, Cephalon
Larry Forti, Pfizer
Laura Bartels, TPNA
Mary Kaysen, Takeda
Michael Brousseau, Alkermes
Paul Kelly, Janssen
Stacy Feeney, Cephalon
Steven Berardi, Amgen
Tracy Wall, Merck

Michael Scovner, M.D., Chair, called the meeting to order at 7:10 p.m. at the DUR Board meeting site in Williston.

1. Executive Session:

- An executive session was held from 6:30 until 7:00 p.m. to discuss Medicaid OBRA'90/Supplemental Rebates and Agreements as provided by 33 VSA § 1998(f)(2).

2. Introductions and Approval of DUR Board Minutes:

- Introductions were made around the table.
- The February 2007 meeting minutes were accepted as printed without amendment.

Public Comment: No public comment.

3. OVHA Pharmacy Administration Updates: *Ann Rugg - Deputy Director, OVHA*

- S115 – Privacy Provision for Prescribing: At the February meeting, Madeleine Mongan, VP for Policy at the Vermont Medical Society, reported on the privacy provision for prescription data. OVHA has provided input to both the Senate Finance and Senate Health and Welfare committees. OVHA will continue to testify in support of this provision.

4. Medical Director Update: *Scott Strenio, M.D. – Medical Director, OVHA*

- No updates, prescriber comments, or other topics for discussion.

5. Follow-up items from Previous Meeting

- Methadone: *Diane Neal, R.Ph., MedMetrics Health Partners (MHP)*
  Contact has been made with Dr. Michael Borrelo from the FAHC Pain Clinic. The plan is for Dr. Strenio and Diane Neal to meet with Dr. Borrelo to discuss recommendations on the use of methadone as a pain medication in light of the FDA's recent alert.

Public Comment: No public comment.

Board Decision: None needed.

- Duplicate Long Acting Narcotics *Diane Neal, R.Ph., (MHP)*
  Deferred until next meeting.

- Vivitrol®: *Diane Neal, R.Ph., (MHP)*
  The pharmacology and clinical studies were reviewed at a previous meeting. The recommendation for this medication is that it be PA required with completion of a Vivitrol® specific PA form required. The only approved indication will be for alcohol dependence (use for opiate dependence will not be approved). The recommendation is that Vivitrol® be provided through the pharmacy benefit only and blocked from the medical benefit. Pharmacies will be required to provide the medication directly to the physician's office.

Public Comment: No public comment.

Board Decision: The Board approved the PA criteria and the Vivitrol® PA form as presented.

6. Review of Newly-Developed/Revised Clinical Coverage Criteria:

Note: All drug/criteria decisions will be reflected in the next PDL and/or Clinical Criteria update.

- Anti-Infectives: Ketolides: *Diane Neal, R.Ph, (MHP)*
  Revised clinical criteria were presented that reflect the FDA restricted approved indications. The use of Ketek® will only be approved for use in community acquired pneumonia and patients will be screened for concomitant medical conditions that place them at risk when receiving this medication.

Public Comment: No public comment.

Board Decision: The revised clinical criteria were unanimously accepted. The board requested that the FDA alert be posted on the web.

- Anti-Infectives: Miscellaneous (Qualaquin®): *Diane Neal, R.Ph, (MHP)*
  The revised clinical criteria were presented. Qualaquin® will be approved only for treatment of malaria. It will not be approved for use in treating leg cramps.

Public Comment: No public comment.

Board Decision: The revised clinical criteria were unanimously accepted.

- Acne Drugs: Oral: *Diane Neal, R.Ph, (MHP)*
  This drug category was updated to include the oral tetracycline products. Generic tetracyclines will be the preferred choice in this sub–category. Additionally, every sub-category was updated to indicate that brand products are non-preferred. As new brands enter the market place they will be automatically added to the PA required section of this class and not brought forward to the Board for full review unless the product has significant differences from products already represented on the PDL.

Public Comment: No public comment.

Board Decision: The revised clinical criteria and expanded drug category were unanimously accepted.

- Acne Drugs: Topical Anti-Infectives: *Diane Neal, R.Ph, (MHP)*
  Every sub-category was updated to indicate that brand products are non-preferred. As new brands enter the market place they will be automatically added to the PA required section of this class and not brought forward to the Board for full review unless the product has significant differences from products already represented on the PDL. No changes were made in the preferred or non-preferred products.

Public Comment: No public comment.

Board Decision: The recommended updates were unanimously accepted.

- Narcotic Short Acting Analgesics: *Diane Neal, R.Ph, (MHP)*
  Branded acetaminophen with oxycodone products were added to the PA required side of this category. Generic acetaminophen with oxycodone products are available without PA. As new brands enter the market place they will be automatically added to the PA required section of this class and not brought forward to the Board for full review unless the product has significant differences from products already represented on the PDL.

Public Comment: No public comment.

Board Decision: The addition of "branded acetaminophen with oxycodone products" to the PA required side of this class was unanimously accepted. The Board requested that an ENT specialist be consulted to discuss the role of non-alcohol containing products (eg. Capital with Codeine®) in patients who have undergone throat surgery as there is some suggestion that non-alcohol containing products are less painful to ingest in these patients.

- Glucocorticoids: Topical: *Diane Neal, R.Ph, (MHP)*
  Every potency level was updated to indicate that brand products are non-preferred. As new brands enter the market place they will be automatically added to the PA required section of this class and not brought forward to the Board for full review unless the product has significant differences from products already represented on the PDL. No changes were made in the preferred or non-preferred products.

Public Comment: No public comment.

Board Decision: The revised clinical criteria were unanimously accepted.

7. Clinical Update: New Drug Reviews: *Diane Neal, R.Ph.(MHP)*

- Exubera® (inhaled insulin) – Not recommended for addition to the PDL. Coverage would require PA with a diagnosis or indication of uncontrolled type I or type II diabetes, the patient will be using Exubera® as an adjunct to long-acting insulin or oral hypoglycemic combination therapy, the patient has a contraindication to subcutaneous injections (latex allergy, dermatologic condition, needle phobia, etc), the patient does not have any of the following contraindications: poorly-controlled asthma, chronic obstructive pulmonary disease or a history of smoking within the past 6 months, and the patient is > 18 years old.

Public Comment: *Larry Forti, Pfizer* – Demonstrated the use of the inhaler for the Board.
Kevin Danielson, Pfizer – Commented on the plans for increased education with diabetes educators.

Board Decision: The Board approved the MHP recommendations as described.

- Cesamet® (nabilone) – Not recommended for addition to the PDL. Coverage would require PA with indication of treatment of nausea and vomiting associated with cancer chemotherapy and failure to respond adequately to conventional antiemetic therapy. The recommended quantity limit per fill would be the quantity needed for a single course of therapy.

Public Comment: No public comment.

Board Decision: The Board approved the MHP recommendations noted above.

- Elaprase® (idursulfase) for Intravenous Infusion – Not recommended for addition to the PDL. Coverage would require PA with a diagnosis or indication of Hunter's Syndrome. It was recommended that Elaprase® be covered only by the pharmacy benefit and blocked from the medical benefit. A quantity limit of the calculated weekly dose was recommended.

Public Comment: No public comment.

Board Decision: The Board approved the MHP recommendations noted above.

8. New Drug Classes:

Note: All drug/criteria decisions from this section will be reflected in the **04/01/07** PDL and/or Clinical Criteria update unless specified otherwise.

- Anticoagulants: *Diane Neal, R.Ph, (MHP)*
  Proposed PDL preferred agents to be warfarin, heparin, Lovenox® and Arixtra®.
  Proposed non-preferred (PA required) agents to include brand Coumadin®, Fragmin® and Innohep®. Current users of Coumadin® would be grandfathered.
  Clinical criteria for approval of non-preferred agents were presented.

Public Comment: No public comment.

Board Decision: The Board approved as recommended.

- Ophthalmics: Wetting Agents *Diane Neal, R.Ph, (MHP)*
  Proposed PDL preferred agents to be artificial tears and lubricants (all generics and brands).
  Proposed non-preferred (PA required) agents to include Lacrisert® and Restasis®. Recommended quantity limits for Lacrisert® is 60 inserts/month and Restasis® is 64 vials/month. Current users of Lacrisert® and Restasis® would be grandfathered.
  Clinical criteria for approval of non-preferred agents were presented.

Public Comment: No public comment.

Board Decision: The Board requested input from an ophthalmologist as to the criteria for the PA required medications. The discussion was tabled for this month and no decision was made.

- Anti-Infectives: Genital Antivirals *Diane Neal, R.Ph, (MHP)*
  Proposed PDL preferred agents to be Aldara®, Condylox Gel® and generic podofilox solution.
  Proposed non-preferred (PA required) agent to be brand Condylox® solution.
  Clinical criteria for approval of Condylox® solution were presented.

Public Comment: No public comment.

Board Decision: The Board approved as recommended.

- Anticonvulsants *Diane Neal, R.Ph, (MHP)*
  Proposed PDL preferred agents to include generic products (many) and the brand name products Carbatrol®, Celontin®, Depakote®, Depakote ER®, Diastat®, Dilantin®, Felbatol®, Gabitril®, Keppra®, Lamictal®, Lamictal® chewable tablets, Lyrica®, Neurontin® oral solution, Phenytek®, Tegretol XR®, Topamax® and Trileptal®.
  Proposed non-preferred (PA required) agents to include Depakene®, Gabarone®, generic lamotrigine chewable tablets, Mysoline®, Neurontin®, Tegretol®, Zarontin® and Zonergan®. Current users of brand Tegretol® would be grandfathered.
  Clinical criteria for approval of non-preferred agents were presented.

Public Comment: No public comment.

Board Decision: The Board approved as recommended.

- Anti-psychotics: Other: *Diane Neal, R.Ph, (MHP)*
  This category was formerly named "Mood Stabilizers". The anticonvulsants that were formerly in this category have been moved to the new anticonvulsant category. The proposed remaining PDL preferred agents to be Equetro® and the generic products lithium carbonate, lithium carbonate SR and lithium citrate syrup.
  Proposed non-preferred (PA required) agents to include brand Eskalith CR® and Lithobid®.
  Clinical criteria for approval of non-preferred agents were presented.

Public Comment: No public comment.

Board Decision: The Board requested that the name of the category be reverted back to "Mood Stabilizers" and that there be a prominent notation to "See also Anticonvulsants". The Board approved the medications in the Preferred and PA required categories as well as the clinical criteria.

9. RetroDUR: *Diane Neal, R.Ph. (MHP)*

Potential RetroDUR initiatives were presented to the Board. The Board was most interested in initiatives that focused on safety and felt that physicians were generally overwhelmed by requests for documentation and action on "best practice initiatives". The Board requested that an examination of high dose acetaminophen dosing be undertaken first, followed by migraine drug monitoring to identify patients receiving high frequency triptan agents without prophylaxis as well as examining high utilizers of controlled medication with duplicate long acting narcotics who may also have multiple prescribers and/or pharmacies. There was interest in looking at patients with hospital admissions for asthma and examining drug therapy pre and post admission.

10. Updated New-to-Market Monitoring Log: *Diane Neal, R.Ph, (MHP)*

- This log shows new entries in the market highlighted in red. The log is informational only. Suggested dates for review are to be used as a guide only. The actual date of review will depend on the complexity of the agenda.
- Coreg® CR was eligible for addition as a line item extension however the Board recommended waiting the usual 6 month new to market period.

Public Comment: No public comment.

Board Decision: The Board approved all MHP recommendations.

11. General Announcements: *Diane Neal, R.Ph, (MHP)*

- RotaTeq® Vaccine
  There had been some concern that there may be an increased risk of intussusception with this vaccine. However, a recent analysis of safety data suggests that this is not the case (presented as informational only).

- Pioglitazone/Rosiglitazone – Increased Fracture Risk
  Dear Health Care Provider letters from the manufacturers of these two products were shared with the Board. The recommendation is that the risk of fracture should be considered in the care of patients receiving these medications and that attention be given to bone health according to current standards of care. The letters will be posted on the web for physicians.

- Zelnorm® (tegaserod)
  The FDA issued a public health advisory regarding Zelnorm®. The drug is being taken off the market because a new safety analysis has found a higher incidence of heart attack, stroke, and worsening heart chest pain with Zelnorm® treatment than with placebo.

Board Decision: The Board recommended blocking of dispensing at the pharmacy and sending patient specific letters to prescribers as well as posting the letter on the web for physician reference.

- Pergolide Products
  The FDA announced a voluntary withdrawal of pergolide products because of the risk of serious damage to patients' heart valves. Physician offices were called for the eight patients identified and a follow-up fax was sent that contained suggested actions. The letter that was faxed was shared with the Board and will also be posted to the web.

- Quantity Limits – Non-managed Drug Classes
  Review of the pharmacy claims data reveals certain drugs that are not in managed classes that tend to be submitted with incorrect quantities primarily due to confusion about billable units or key stroke errors. It was proposed that a category be established in the PDL where quantity limits could be documented for various medications in non-managed classes.

  Board Decision: The Board recommended the establishment of a listing of quantity limits for medications that are not in managed classes.

12. Adjourn: Meeting adjourned at 9:15 p.m.

Next DUR Board Meeting
Tuesday, May 8, 2007
7:00 - 9:00 p.m.*
EDS Building, OVHA Conference Room
312 Hurricane Lane, Williston, VT
(Entrance is in the rear of the building)

* The Board meeting will begin at 6:30 p.m. and the Board will vote to adjourn to Executive Session to discuss Medicaid OBRA'90/Supplemental Rebates and Agreements as provided by 33 VSA § 1998(f)(2). The Executive Session is closed to the public.